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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,205	12/10/2001	Christa Tauer	V-258.00	9038

7590

11/05/2002

Baxter Healthcare Corporation
P.O. Box 15210
Irvine, CA 92614

EXAMINER

LI, BAO Q

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 11/05/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/006,205

Applicant(s)

TAUER ET AL.

Examiner

Bao Qun Li

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-51 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14, drawn to a method for producing complete hepatitis A virus particle by using degrading agent and protease, classified in class 435, subclass 235.1.
- II. Claim 15-25, drawn to a method of producing of a purified mature hepatitis A virus comprising the steps of treating the HAV preparation with degradation agent and a protease, classified in class 435, subclass 308.1.
- III. Claims 26-27, drawn to a method for producing of a purified complete HAV particle by filtration, classified in class 530, subclass 228.
- IV. Claims 28-29, drawn to a method for producing of a purified complete HAV particle by filtration plus concentration, classified in class 530, subclass 414.
- V. Claims 30-31, drawn to a method for isolating complete HAV particle from a cell-free culture supernatant free from HAV precursor polypeptide by treating the HAV preparation supernatant with agents, classified in class 435, subclass 4.
- VI. Claims 32, drawn to a method for isolating mature HAV particle from a cell culture supernatant free from HAV precursor polypeptide and cell culture protein, classified in class 530, subclass 427.
- VII. Claims 33-36, drawn to a product comprising complete HAV particle free from HAV precursor and cell culture protein, classified in class 435, subclass 235.
- VIII. Claims 37-40, drawn to a preparation of mature HAV particle free from HAV precursor and contaminating cell or cell culture protein, classified in class 424, subclass 226.1.
- IX. Claim 41-43, drawn to a method for producing HAV vaccine comprising complete HAV or mature HAV virions, classified in class 424, subclass 205.1 .
- X. Claim 44, drawn to a method for producing an inactivated HAV vaccine, classified in class 424, subclass 177.1.
- XI. Claims 37 and 45-49, drawn to a HAV vaccine comprising the mature HAV virions and immune stimulating agent, classified in class 424, subclass 149.1.

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XII. Claims 37, 45-48 and 50, drawn to a HAV vaccine comprising the mature HAV virions and HBV antigen, classified in class 425, subclass 237.1.

XIII. Claims 37, 45-48 and 51, drawn to a HAV vaccine comprising the mature HAV virions and other antigen, classified in class 424, subclass 202.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions VII, VIII and XI-XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to structurally different agents used for different purpose and produce different biological effects, e.g. the vaccine composition of Group XI only comprises mature HAV and immune stimulatory agent, whereas the vaccine composition of XII comprises HAV and HBV antigen.

Inventions I-VI and IX-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to different method, e.g. the method of Group X only is for producing inactivated HAV agent, whereas the method of Group IX is for producing a live complete or mature HAV virus particle.

Inventions of group III and XII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product of group XII can be made by the recombination technique, rather than direct isolation, whereas the method for isolating the HAV virus disclosed by the Group III, can be used for isolating recombinant protein, rather than virus.

Because these inventions are distinct for the reasons given above and have acquired a separate searches, the restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

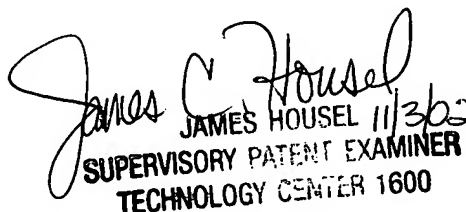
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

November 1, 2002


JAMES HOUSEL 11/3/02
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600